[redacted]

P-18-0169

Chemical Name: [redacted]

CASRN: [redacted]

ASSIGNMENTS	NAME	DATE
SAT Chair	Doritza Pagan-Rodgriguez	7/10/2018
HH Hazard Assessor (A)	Keith Jacobs	7/10/2018
HH Hazard QC Reviewer (A)	Susan Laessig	7/11/2018
HH Risk Assessor FOCUS (B)	Chris Brinkerhoff	7/19/2018
HH Risk QC Reviewer (B)	Sailesh Surapureddi	7/18/2018

Human Health Report Status:		DATE COMPLETED
X	HAZARD DRAFT- Pending Review	7/10/2018
X	HAZARD REVIEWED	7/11/2018
X	HAZARD FINAL	7/12/2018
X	RISK DRAFT- pending review	7/18/2018
X	RISK REVIEWED	7/18/2018
X	RISK-FOCUS FINAL- Uploaded	7/19/2018
	POST-FOCUS UPDATE DRAFT	
	POST-FOCUS UPDATE FINAL- Uploaded	

Updated 10/29/18:

Updated risk statement as follows:

Irritation and sensitization hazards to workers were identified via inhalation and dermal exposures based on the acrylates/methacrylates category. Risks for these hazard endpoints were not quantified due to a lack of dose-response for this hazard, but will be mitigated if exposures can be controlled by the appropriate use of appropriate PPE, including impervious gloves and a respirator.

1 HUMAN HEALTH SUMMARY

[redacted]

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties and by comparing it to structurally analogous chemical substances for which there is information on human health hazard and other structural information.
Based on the hazard determination and available quantitative and qualitative risk information, EPA concludes that there is risk for the PMN substance.

1.1 Hazard Summary

- Absorption of the high molecular weight species (> 1000) is nil all routes, absorption of the low molecular weight fractions (0.5% < 1000 and 0.5% < 500) is expected to be poor all routes.
- Developmental toxicity, irritation and neurotoxicity hazards were identified based on analogy to triethylamine.
- Irritation and sensitization hazards were identified based on information in the SDS and acrylates/methacrylates category.
- There is minimal concern for systemic, developmental and oncogenicity from acrylate moieties based on low percentage of LMW species and Acrylate FGEW = [redacted].
- Lung effects from lung overload was not identified for this high molecular weight polymer because the substance is dispersible.

1.2 Risk Summary

1.2.1 Workers

Irritation and sensitization hazards to workers were identified via inhalation and dermal exposures based on the acrylates/methacrylates category. Risks for these hazard endpoints were not quantified due to a lack of dose-response for this hazard, but will be mitigated if exposures can be controlled by the appropriate use of appropriate PPE, including impervious gloves and a respirator.

Risks were not identified for workers for systemic effects (developmental and neurotoxicity) via inhalation (MOE = 331; benchmark MOE = 100) or dermal contact (MOE = 149; benchmark MOE =100) based on quantitative hazard data for an analogue of a for a component of the PMN (triethylamine).

1.2.2 General Population

Risks were not identified for the general population for sensitization and irritation via drinking water exposure since these concerns are expected to be mitigated by dilution in the media.

Risks were not identified for general population for systemic effects (developmental and neurotoxicity) via oral ingestion of drinking water based on quantitative hazard data for an analogue of a component of the new chemical (triethylamine). (MOEinfant = 67220; MOEadult=280306; benchmark MOE = 100).

1.2.3 Consumers

Risks to consumers were not evaluated because consumer use was not identified as a condition of use.

1.3 Potentially Useful Information:

1.3.1 Assumptions and Uncertainties

Absorption of the PMN/LVE is based on p-chem properties

The POD for the triethylamine counterion is based on read-across to an analog

Based on a smaller % of low-molecular-weight species and relative high FGEW [redacted], systemic concerns for acrylates are not expected.

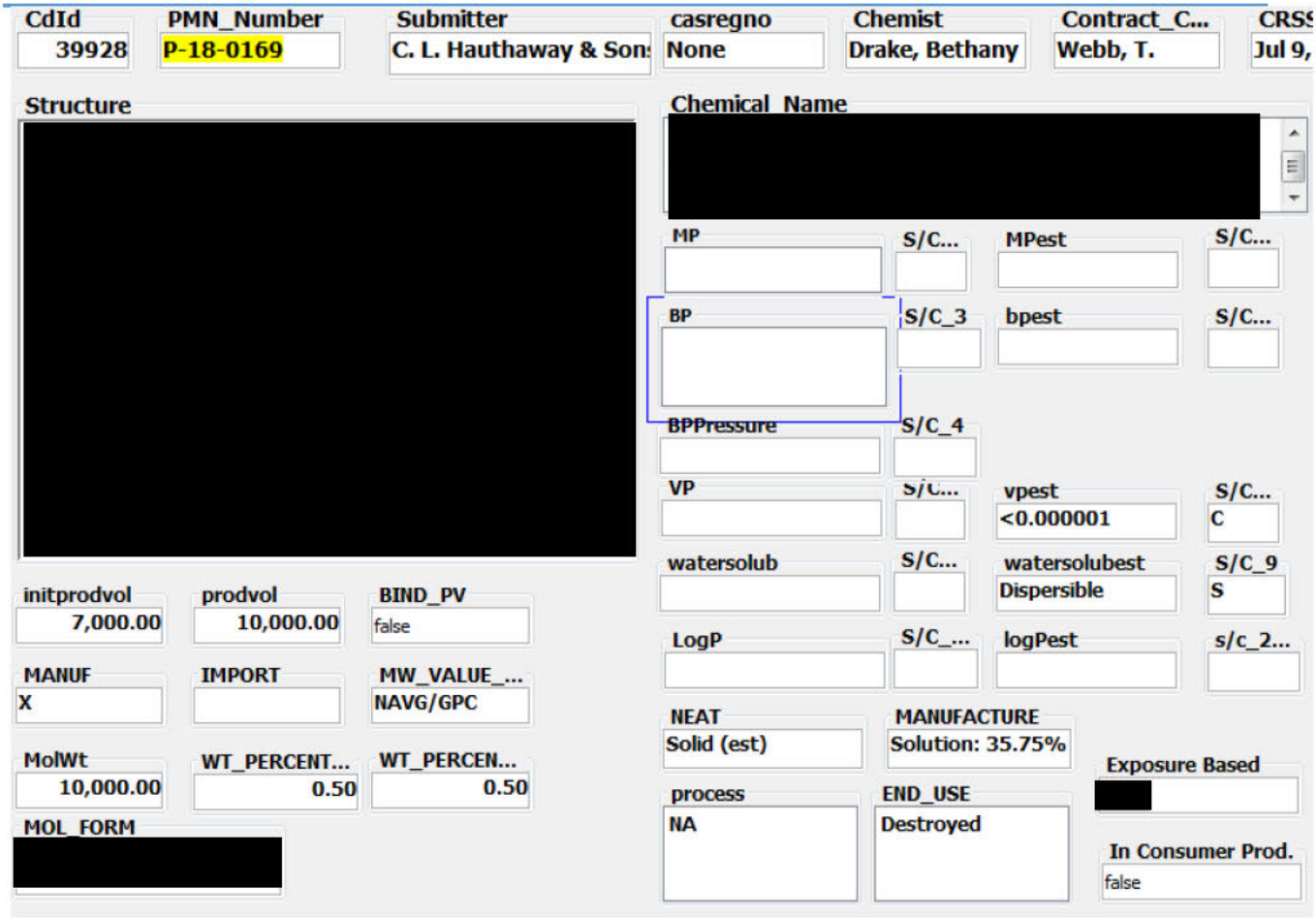
1.3.2 Potentially Useful Information

Potentially useful information would inform understanding of absorption, the specific target organ toxicity, irritation, sensitization and developmental toxicity.

[redacted]

2 HUMAN HEALTH HAZARD- PART A

2.1 Chemistry Summary



2.1 SAT Summary

2.1.1 PMN Health Rating

H = 2

2.1.2 SAT Key Words

DEV, IRRIT, NEURO,SENS

2.1.3 Absorption

Absorption of the high molecular weight species (> 1000) is nil all routes, absorption of the low molecular weight fractions (0.5% < 1000 and 0.5% < 500) is expected to be poor all routes.

2.1.4 SAT Health Summary

The PMN contains [redacted]% triethylamine. There is concern for developmental toxicity, irritation and neurotoxicity based on triethylamine.

Concern for irritation and sensitization based on information on SDS and acrylates/methacrylates category.

[redacted]

There is no concern for systemic, developmental and oncogenicity from acrylate moieties based on low content of LMW species and Acrylate FGEW = [redacted] For instance, data on smaller compounds with single acrylate moieties in the document, Data Screening Assessment Acrylates and Methacrylates Group, Sept 2017, Environment and Climate Change Canada - Health Canada, show a trend of decreasing toxicity with increased molecular weight.

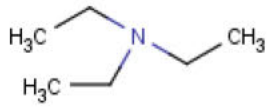
Concern for lung effects from lung overload was not identified for this high molecular weight polymer because the substance is dispersible.

2.1.5 PMN Data (Study summary, POD)

No data available.

2.1.6 Analog Data (analog, structure, study summary, POD)

Triethylamine (TEA) – CAS RN 121-44-8



- NOAEL = 8.5 mg/kg; Lowest POD is for Developmental toxicity based on read across to dimethylcyclohexylamine (DMCHA) based on decreased pup weights (dietary/oral administration) (OECD SIDS 2012 for tertiary amines).
- 1 study injected TEA into chicken embryos and caused embryonic death per HSDB (Korhonen et al 1983).
- Also data for TEA on concerns for acute effects, corrosivity/irritation, lung inflammation. Also a CNS stimulant per HSDB, and causes vision problems (gas). Liver, kidney, and heart effects seen in rabbits exposed to TEA vapor.

[redacted]

Not absorbed through the skin, neat not absorbed from the lung and GI tract (pchem); if in solution expect poor absorption of the low molecular weight fractions (16% <500, 30% <1000) from the lung and GI tract (pchem), expect poor Michael addition to the acrylate moieties (FGEW = 1400 by charge, ca. 300 as drawn). Concern for mutagenicity, oncogenicity, developmental, liver, and kidney toxicity, sensitization, and irritation from the acrylate.

[redacted]

2.1.7 Other Information (SDS, structural alert or component of interest, basis, etc.)

Two SDS submitted. They may be on monomer components but it is unclear

SDS #1 – [redacted]

[redacted]

Hazard Statement:

H302	Harmful if swallowed.
H315	Causes skin irritation
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.

Toxicological Information section cites a repeated dose NOAEL=25mg/kg for an oral rat study, and negative result for mutagenicity

SDS #2 – [redacted]

[redacted]

Hazard Statement:

H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction
H318 Causes serious eye irritation.
H335 May cause respiratory irritation.
H360 May damage the unborn child.

2.1.8 Exposure Routes of Interest

	Route of Interest
X	Inhalation:
X	Dermal:
X	Ingestion:

2.2 Human Health Category (From US EPA 2010 document)

Chemical Category: Acrylates/Methacrylates
Chemical Category Health Concerns: sensitization/irritation
Category Testing Strategy: none for health

[redacted]

2.3 Point of Departure Selected and Basis

2.3.1 POD for triethylamine (based on data from read across chemical DMCHA)

POD type: NOAEL
POD Value: 8.5mg/kg
POD Chemical: DMCHA
POD Route: Oral
POD Hazard Endpoint: developmental toxicity
POD Basis: POD as identified by OECD SIDS based on read across chemical (DMCHA) for triethylamine
POD Benchmark MOE: 100
Reference: OECD SIDS CoCAM 2, 17-19 April 2012
https://hpvchemicals.oecd.org/ui/handler.axd?id=B014325A-B284-4082-8ADC-D4F07BD86FB3

Note: Should only be applied to [redacted] of the PMN based on the % of TEA present

3 HUMAN HEALTH RISK (PART B)

3.1 USES and EXPOSURES

3.1.1 Uses

[redacted]

3.1.2 Worker Exposure

3.1.2.1 Inhalation

PDR: [redacted] mg/day over 250 days/yr. Exposure to Mist (non volatile). Basis: [redacted]; OSHA PNOR PEL Limiting Model. Cm = 5.4 mg/m^3 over 8 hr/day.

3.1.2.2 Dermal

PDR: [redacted] mg/day over 250 days/yr. Exposure to Liquid at 35.75% concentration. Basis: [redacted]; EPA/OPPT 2 Hand Dermal Contact with Liquids Model.

3.1.3 General Population Exposure:

3.1.3.1 Drinking Water

Drinking water ingestion with ADR as high as **7.98e-4 mg/kg/day** and LADD as high as **7.85e-6 mg/kg/day**

3.1.3.2 Fish

Based on fate assessment, the PMN **was not** evaluated as persistent and bioaccumulative

[redacted]

3.1.3.3 Air/Inhalation

- Exposure from predicted environmental fugitive air release(s) was not assessed for the **acute and chronic scenarios**, as they are below modeling thresholds.
- Exposure from predicted environmental stack incineration release(s) was not assessed for the **acute and chronic scenarios**, as they are below modeling thresholds.

3.1.4 Consumer Exposure

No identified consumer exposures

3.2 RISK CALCULATIONS

3.2.1 Worker Calculations

Irritation and sensitization hazards to workers were identified via inhalation and dermal exposures based on the acrylates/methacrylates category. Risks for these hazard endpoints were not quantified due to a lack of dose-response for this hazard, but will be mitigated if exposures can be controlled by the appropriate use of appropriate PPE, including impervious gloves and a respirator.

Risks were not identified for workers for systemic effects (developmental and neurotoxicity) via inhalation (MOE = 331; benchmark MOE = 100) or dermal contact (MOE = 149; benchmark MOE =100) based on quantitative hazard data for an analogue of a component of the PMN (triethylamine).

[redacted]

Focus Worker Calculations MOE = (POD x Abs Rate) / ((PDR x Abs Rate) / BW) Acceptable MOE ≥100																		
Exposure Scenarios and Values[1]		POD= N/LOAEL (mg/kg/day)		POD Route Absorp. Adj[2]			Potential Dose Rate (mg/day)		Exposure Route Absorp Adj[2]		Structural Alert/ Component as % of PMN		Avg BW[3] All Adults, 80 (kg)			Margin of Exposure[4] (POD/PMN Dose)	Inhalation Fold" Factor[5] (Benchmark/ MOE)
WORKER RISK																		(NOAEL=100)
Highest/Worst Case Doses from Engineering Report																		
Inhalation	(	8.5	x	100%	)	÷	(	[redacted]	x	100%	x	[redacted]%	÷	80	)	=	331	0.3
Dermal	(	8.5	x	100%	)	÷	(	[redacted]	x	15%	x	[redacted]%	÷	80	)	=	149	N/A

[1] Inhalation doses in mg/day are from the Engineering Report generated using ChemSTEER. Unless otherwise stated, the assumption is an 8-hr day.The EPA/OPPT 2-Hands Dermal Contact with Liquids Model calculates worker dermal exposures to a liquid. Model assumptions are: (1) surface area of contact equals two hands (1,070 cm2); (2) high-end default value of quantity remaining on skin = 2.1 mg/cm2 (low-end default = 0.7 mg/cm2); (3) weight fraction of chemical in liquid; (4) 1 contact/worker-day; (5) no use of controls or gloves to reduce exposure; (6) exposure duration = 1 to 4 hours based expectation that worker will, at a minimum, thoroughly wash hands at lunch or end of the day.

[2] Absorption adjustments for Focus - Assume 100% for POD; For Exposure. If risks, consider adjustments for absorption,etc.

[3] USEPA 2011. Exposure factors handbook, final report, EPA/600-R09/052F, 2011, Chapter 8 Body Weight Studies,Table 8-1, Recommended Values for Body Weight http://www.epa.gov/ncea/efh/pdfs/efh-chapter08.pdf

[4]Benchmark (Acceptable) MOEs are 100 for NOAEL-based assessment and 1000 for LOAEL-based assessment.

[5] Fold factor = value to be applied to bring INHALATION MOE up to acceptable level, used by the CEB Industrial Hygenist to determine respirator recommendations. NOAEL-based fold factor = 100/MOE; LOAEL-based fold factor = 1000/MOE.

POD based on read across data for triethylamine (TEA) substructure ([redacted] of the PMN) for developmental toxicity effects. Dermal exposure adjusted to poor (15%) based on SAT and assumed 100% for the analog TEA because TEA is a much smaller structure than the PMN.

3.2.2 General Population Calculations

Risks for the general population for irritation and sensitization via oral ingestion of drinking water were not quantified due to a lack of dose-response for this hazard and this effect is considered less likely via this route and at the low estimated exposures (7.98E-4 mg/kg/day). Risks were not identified for general population for systemic effects (developmental and neurotoxicity) via oral ingestion of drinking water based on quantitative hazard data for an analogue of a component of the new chemical (triethylamine). (MOEinfant = 67220; MOEadult=280306; benchmark MOE = 100).

[redacted]

Focus General Population and Consumer MOE Calculations MOE = (POD x Abs Rate) / ((PDR x Abs Rate) / BW) Benchmark (acceptable) MOE ≥100																		
Exposure Scenarios and Values[1]		**POD= N/LOAEL (mg/kg/ day)**		**POD Route Absorp Adj[2]**			**Exposure Acute Dose Rate (mg/kg/day)**		**Exposure Route Absorp Adj[2]**		**Multiplier for Sensitive Sub-populations[4]**		**Structural Alert/ Component as % of PMN**			**Margin of Exposure (POD/PMN Dose)**
GENERAL POPULATION RISK																	(NOAEL=100)	
Highest/Worst Case Doses from Exposure Report																		
Drinking Water	(	8.5	x	100%	)	÷	(	7.98E-04	x	100%	x	1.00	x	[redacted]%	)	=	280306	
Drinking Water	(	8.5	x	100%	)	÷	(	7.98E-04	x	100%	x	4.17	x	[redacted]%	)	=	67220	

[1] General Population and Consumer ingestion Acute Dose Rates are from the Exposure Report and are generated using E-FAST which assumes a 100% absorption rate, and uses an average adult body weight of 80 kg. Consumer ADRs are generated using the Consumer Exposure Module within the E-FAST CBI version called "NCEM2" model.

[2] Absorption adjustments for Focus: Assume 100% POD; if risks, consider adjusting for absorption, etc.

[3] Benchmark (Acceptable) MOEs are 100 for NOAEL-based assessment and 1000 for LOAEL-based assessment.

[4] Multiplier based on increased drinking water consumption for infants. Multiplier would be less for older populations, so this value is worst-case.

3.2.3 Consumer Calculations

Risks to consumers were not evaluated because consumer use was not identified as a condition of use.